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June 2019

Committee Secretary
State Development, Natural Resources and Agricultural Industry Development Committee
Parliament House
George Street
Brisbane Qld 4000

05/06/2019

Dear Dr Jacqui Dewar,

Re: Inquiry into the Medicines and Poisons Bill 2019

I INTRODUCTION

A *Background*

The Hon Dr Steven Miles MP introduced the Medicines and Poisons Bill 2019 ('Bill') to the legislative assembly on 14 May 2019. The Bill was referred to the committee and submissions were invited from interested parties. We write to submit our views on the regulatory framework within the scope of this inquiry.

The authors are registered pharmacists under the *Health Practitioner Regulation National Law (Queensland)*. The authors currently practice in the community pharmacy sector. Their experience includes rural and regional community pharmacy practice and accreditation to undertake medication management reviews.

The structure of this submission has been designed to assist the committee perform its function of reviewing the regulatory framework. A solid bullet point identifies the relevant provision in the Bill or Medicines and Poisons (Medicines) Regulation 2019 ('Regulation') and outlines the issue for consideration. An explanation is provided where possible underneath each solid bullet point to draw attention to the consequences of each provision. Finally, a possible recommendation has been included for the committee to consider.

B *Methodology*

The authors adopted the following methodology in preparing this submission. The draft Bill was reviewed as a whole document. The draft Regulation was reviewed in the context of the authorising Bill and read as a whole document. Explanatory notes for the Bill and Regulation were also reviewed, in addition to the First Reading Speech. The authors reviewed all the information in the context of their experience.

C *Acknowledgements and contact details*

The views expressed in this submission are solely those of the authors. Both authors contributed equally to this submission.

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II SUBMISSION COMMENTS ON MEDICINES AND POISONS BILL 2019 AND CORRESPONDING DELEGATED LEGISLATION

A *Medicines and Poisons Bill 2019*

- cl 18 (deals with includes manufacture) and cl 21 (manufacture includes cl 21(b) compounding)
  - clarify that pharmacists do not need a manufacturing licence as sch 9 reg 15 of Medicines and Poisons (Medicines) Regulation 2019 (Qld) authorises compounding.
  - Pharmacists should not be required to hold a manufacturing licence to compound medicines. Compounding is within the scope of practice of a pharmacist
  - Reason: there is uncertainty regarding interpretation and possible exposure to punishment – pharmacists may commit an offence under cl 33(a) for manufacturing that is not performed in the authorised way. Therefore, pharmacists would have to argue that they had a reasonable excuse under cl 33(b); the reasonable excuse being sch 9 reg 15.

- cl 92 Substance Management Plans – in the definition section of *substance management plan*, insert the word 'reasonably' before the word 'foreseeable'
  - Reason: unrealistic expectation and possible exposure to punishment under cl 93(1) – a risk that is 'foreseeable' may include a farfetched or fanciful risk, an unlikely risk and an absurd risk. These risks would all have to be accounted for in a substance management plan regarding a 'foreseeable' risk.

- cl 127 – Public Warnings – infringes on rights and liberties and exposes innocent pharmacists to harmful consequences
  - cl 127(1)(a) a public warning may be issued for contravention resulting in notification action being taken (cl 127(6)(a) notification action means a compliance notice and cl 108 provides that it is appropriate to give a person an opportunity to rectify a contravention by issuing a compliance notice). A contravention could vary in degree of severity.
  - cl 127(3)(a): it is unclear what is meant by the phrase 'in the public interest.' Is it within the scope of public interest to merely be aware of any activity undertaken by a regulator? If so, then according to cl 127(6) *'notification action'* subsection (a) a compliance notice for a trivial matter is a notification action (ie. an activity) undertaken by a regulator. This could therefore form the basis for a public warning.
  - Would it be more appropriate to say that the scope of public interest relates to protection from likely serious harm? This ensures that public warnings are only issued for serious breaches. Furthermore, this is consistent with reasons given in the explanatory notes.
  - cl 127(5) there is no liability for the State – given the above reasons there should be an amendment to say: 'if a compliance notice or recall order is rectified the State must publish a correction notice with the same notoriety as the original public warning.' There is also a concern if a public warning is wrongfully published.

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- cl 232(2) Extended Practice Authorities – if not adopting an entity's code, guideline, standard or protocol, a new provision should be inserted which requires: the chief executive must consult with relevant professional bodies within the industry. A similar provision is already included in cl 234 of the Bill.

B *Medicines and Poisons (Medicines) Regulation 2019*

- Endorsements under sch 4 reg 3 – Prescribing by dentists
  - The regulation authorises a dentist to prescribe for an indication which may be outside the scope of practice of a dentist.
  - This puts the patient at risk of harm and is inconsistent with the purpose of the Medicines and Poisons Bill 2019.
  - In sch 4 reg 3(1), prior to the words 'a dentist may prescribe' insert the qualifying words 'to the extent of recognised dental practice'.

- sch 9 part 2 div 1 – Treatment dose – pharmacists are not authorised to give a treatment dose under this division.
  - The drafting is inconsistent with ch 2 reg 64(2). The provision expressly states that pharmacists may give a treatment dose. However, a treatment dose is not authorised in sch 9 part 2 div 1. Furthermore, ch 2 reg 10 prescribes a regulated activity for the purpose of cl 54(1) of the Medicines and Poisons Bill 2019 (Qld). Therefore, a pharmacist giving a treatment dose would be unauthorised according to cl 54(1) of the Bill. Consequently, an offence will be committed under cl 35 of the Medicines and Poisons Bill 2019 (Qld).
  - In sch 9 part 2 div 1, after reg 2, insert a new regulation 'reg 2A Giving a treatment dose' which authorises a pharmacist to give a treatment dose.

- sch 9 reg 2 – dispensing
  - The provision does not expressly state that a pharmacist may retain possession of a prescription for the time reasonably required to perform the regulated activity that is authorised. Therefore, possession is only implied into the regulation.
  - A pharmacist may be required to retain possession of a prescription to confirm with the prescriber: the authenticity of the prescription; or a suspicion that the prescription contains an error.
  - This is inconsistent with the current *Health (Drugs and Poisons) Regulation 1996* (Qld) regs 82(4), 193(4) which allows a pharmacist to retain possession of a prescription.
  - Insert a new sub-regulation 'reg 2(3) a pharmacist may retain possession of a prescription for the time reasonably required to do a thing under the Act or this Regulation.'

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- sch 9 reg 4(2): labelling S3 medicines
- The label only requires the contact details of the pharmacist. It does not require dispensing instructions to be typed on a label by the pharmacist. Schedule 9 reg 4(2)(b) suggests that the manufacturer's instructions are preferred over a pharmacist using clinical judgement when including or omitting instructions on a label. Pharmacists are medicines experts and are in the best position to ensure medicines are used safely and effectively. One way that pharmacists achieve this is by attaching a label with directions for use of the medicine.
- Sch 9 reg 2(a) requires the contact details of the individual pharmacist to be included on a label. This is unnecessary. It would be more appropriate for the label to include the contact details of the pharmacy dispensing the medicine.
- In sch 9 reg 2(a) replace the word 'pharmacist' with 'pharmacy'
- The labelling requirements from part 2 section 1 of the SUSMP introduced into the regulation by ch 6 reg130(1) should apply to the labelling of S3 medications.
- Ensuring that a label with instructions for use is affixed onto an S3 medicine aligns with the purpose of the Bill. Therefore, the likelihood of medicine-related harm is reduced.

- sch 9 reg 6(2) requires a life-threatening situation if a pharmacist is to provide an urgent supply of a diversion risk medicine.
- This creates an uncertainty and significantly limits possible scenarios when supply might be considered appropriate. For example: tramadol for analgesia or pregabalin for neuropathic pain are not life-threatening conditions. However, patients with these conditions will suffer significant morbidity if they are unable to access an urgent supply, especially in rural areas.
- Omit sch 9 reg 6(2).

- sch 9 reg 6(4)(b) – consider changing '3-days supply' to 'minimum standard pack.'
- A 3-day supply of medication is insufficient for continuity of patient care in circumstances where a patient is unable to obtain a prescription from a prescriber within 3 days. Limiting an urgent supply to 3-days risks unnecessary patient harm. This problem is highlighted in rural areas where access to a prescriber is limited.
- In sch 9 reg 6(4)(b) omit the words '3 days supply of the medicine' and insert 'the minimum standard pack.'
- This would be consistent with the drafting in sch 9 reg 6(4)(a).
- Alternatively, the provision in sch 9 reg 6(4)(b) could be changed to 'one blister sheet' where the medicine is available as a blister pack. Consequently, there would need to be a similar amendment in sch 9 reg 6(4)(a) to account for medicines packaged in a bottle. For example, in sch 9 reg 6(4)(a) after the word 'ointment' insert the word 'bottle'.

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- sch 9 reg 11 – Possession – pharmacists are not expressly authorised to possess, possession is only implied
  - Reason: uncertainty regarding interpretation and possible exposure to punishment – pharmacists may commit an offence under cls 34, 35 of the Medicines and Poisons Bill 2019 (Qld).
  - After buying stock, a pharmacist is required to maintain possession of the stock until dispensing or supplying the medicine. Therefore, it is imperative that pharmacists are authorised to possess medicines in order to practice their profession.
  - In sch 9 reg 11(1) after the word 'buy' insert the words 'and possess.'

- sch 9 reg 16 – disposing of waste
  - A pharmacist may only dispose of waste by giving it to another person (ie. indirect disposal of waste). Consequently, a pharmacist is not authorised to directly dispose of waste under ch 2 reg 74 (the waste must first be given to someone who is authorised).
  - This is inconsistent with achieving the purpose of the Medicines and Poisons Bill 2019 (Qld) and a pharmacist's knowledge and qualification.
  - The drafting is also inconsistent with provisions which allow for the disposing of waste directly by a medical practitioner (sch 6 reg 8) and dental practitioner (sch 4 reg 6)
  - Furthermore, the drafting is inconsistent with reg 171(1)(f) of the *Health (Drugs and Poisons) Regulation 1996* (Qld) which currently allows a pharmacist to directly dispose of a restricted drug. Therefore, the new provision reduces the scope of practice of a pharmacist.
  - Additionally, a pharmacist may commit an offence under cl 42 of the Medicines and Poisons Bill 2019 (Qld) if they directly dispose of an S8 medicine in accordance with ch 2 reg 74 of the regulation.
  - In sch 9 reg 16, omit the words 'by giving it to another person' and omit regs 16(a), (b). Insert a new sub-regulation 'reg 16 (2) the pharmacist must comply with chapter 2, part 2, division 8 when disposing of the waste.'

- sch 9 regs 18, 20 – inconsistent drafting. Hospital technicians can possess medicines under the supervision of a pharmacist, but community pharmacy assistants must be under direct supervision.
- In sch 9 reg 20, omit the word 'direct.'
- This provides for consistency in drafting. Furthermore, the qualifications between hospital technicians and community pharmacy assistants are generally regarded as equivalent.

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- sch 9 reg 21 – selling. The words 'direct supervision' are a new inclusion and reduce the scope of practice pharmacy assistants that is currently authorised under reg 258 of *Health (Drugs and Poisons) Regulations 1996* (Qld).
- Direct supervision also places additional administrative burden on pharmacists to be directly involved in supervising.
- Furthermore, it would not be practical in circumstances where a pharmacist is providing direct pharmaceutical care (eg. dispensing or counselling) to simultaneously supervise assistants directly. Direct supervision would unnecessarily interrupt a pharmacist and expose patients to a risk of harm.
- Omit the word 'direct.'

- sch 9 reg 15 – compounding
- Compounding is only authorised in relation to a patient. A patient is defined in the dictionary in sch 20 to mean a 'person.' Therefore, compounding is not currently authorised for an animal.
- In sch 9 reg 15(1), on the second line of the provision after the words 'a patient' insert 'animal's owner or animal.'
- In sch 9 reg 15(1), on the third line of the provision after the words 'the patient' insert 'or animal.'
- In sch 9 reg 15(2), after the words 'a patient' insert 'animal's owner or animal.'
- Reasoning: pharmacists are medicines experts. It is within the scope of practice of a pharmacist to compound for an animal.

- ch 2 reg 14(2) 'recognised therapeutic practices for appropriate treatment of patients'
- Clarify what is a 'recognised therapeutic practice' as this is not defined in the dictionary in sch 20.
- 'Off-label use' would not be considered 'recognised.' Therefore, dealing with a medicine in a way that constitutes 'off-label use' would not satisfy ch 2 reg 14. Consequently, the use would be unauthorised under cl 54 of the Bill and an offence would be committed under cls 35, 38.
- Prescribing more than the official dose is authorised under reg 190(2)(h) of the *Health (Drug and Poisons) Regulation 1996* (Qld). It appears that prescribing more than the official dose under the proposed new regulations wold be inconsistent with a 'recognised therapeutic practice.' Therefore, the action would be unauthorised under cl 54 of the Bill and an offence would be committed under cls 35, 38.
- The word 'patients' does not include an animal according to the dictionary definition of *patient* in sch 20. After the word 'patients' insert the words 'or animals.'
- The regulated activity mentioned is 'dispensing.' The words 'selling' and 'compounding' are not included. This implies that a therapeutic need is only required for dispensing and not for selling S2 or S3 medicines or compounding.
- In ch 2 reg 14(2), after the word 'dispensing' insert: the word 'selling' and the word 'compounding.'
- In the dictionary in sch 20, insert a new defined term 'recognised therapeutic practice'.

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- ch 2 reg 22 definition of 'electronic communication' subsection (a) – query use of the phrase 'photograph sent digitally'
- If a photograph could be sent digitally via a mobile phone text message or app it would be a *non-compliant electronic communication* according to the definition in ch 2 reg 22. In what circumstances could a photograph be sent digitally and comply with the definition of *electronic communication*? Consider omitting the words 'or photograph' from the definition of *electronic communication*.

- ch 2 reg 24 – 'use terms or symbols used in the ordinary practice of profession'
- Potential for ambiguity and misinterpretation of a term or symbol. Terms and symbols mean different things in different professions and in different circumstances. This puts the patient at risk of medicine related harm.
- Consider the addition of a new 'reg 24(c)' to qualify. For example: reg 24(c)(i) 'only those terms or symbols that are universally recognised may be used;' and (ii) 'plain English is preferred.'

- ch 2 reg 26(2)(b)(i) – the next business day requirement if sending a paper prescription for a S8 medicine is not practical.
- Consider omitting reg 26(2)(b)(i). Therefore, all prescriptions must be given to a pharmacist within 7 days. This allows adequate time for postage.

- ch 2 reg 33(3)(b) the words 'in which' are unclear – should the words read 'which must elapse before'?
- The word 'in' is used in this context as a preposition and appears to indicate a meaning of 'occurring during a period of time.'
- Reason for change: the intention of a repeat interval is to allow for appropriate access, whilst simultaneously restricting a person from obtaining excessive quantities of a medicine known to cause harm.

- ch 2 reg 33(2)(k) – drafting creates uncertainty and is inconsistent with ch 2 reg 37(e)
- The phrase 'contact details' is unclear. A prescription should contain the name and address of the patient or animal's owner. This would be consistent with the drafting in ch 2 reg 37(e).
- omit 'contact details' and insert 'name and address.'

- ch 2 reg 35(3) – possible drafting error
- The word 'prescriber' in this context is unclear.
- The word should be 'person' to indicate someone who is authorised to supply (ie. a dispenser).
- Omit the word 'prescriber' and insert 'person'.

- ch 2 reg 39 – drafting error
- After the word 'subdivision' insert – 'applies'

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- ch 2 reg 50 – every time a pharmacist is dispensing a 'diversion-risk' medicine, they need to ensure that the prescription has been given by a prescriber. The example provided is 'attempting to contact' the prescriber.
- It is not practical to contact a prescriber for every prescription. The time taken to fulfil this requirement would result in a patient's ability to access a medicine being decreased.
- This creates unnecessary administrative burden for both pharmacists and prescribers.
- Omit ch 2 reg 50.

- ch 2 reg 51(2)(b) – requirement for a prescriber to approve of dispensing a generic medicine (ie. by not placing a mark in the box titled 'do not substitute.')
- Pharmacists are medicines experts and together with patient consent can safely dispense a generic medicine with appropriate counselling. This section effectively restricts a pharmacist from practicing to their full scope of practice. Furthermore, it places unnecessary financial burden on the public healthcare system where dispensing a generic medicine is both safe and effective; in circumstances where: a pharmacist has expert pharmaceutical knowledge, a patient consents to the dispensing of a generic medicine and a prescriber does not allow for the activity to occur.
- The need for reg 51(2)(b) is therefore unnecessary.
- Omit reg 51(2)(b).
- Omitting this provision would also assist with partly aligning the legislative intention in reg 51(3) for the dispensing of generic medicines in public hospitals.
- Alternatively, a new sub-regulation could be inserted: 'reg 51(2)(d) either – (i) options (a), (b) and (c) apply; or (ii) both (a) and (c) apply.'

- ch 2 reg 52(3) – inconsistent drafting
- This provision is inconsistent with sch 9 reg 6 which allows for a 3-day supply of S4 medicines in urgent circumstances.
- In ch 2 reg 52(2), after the words 'maximum period of' omit the Arabic numeral '2' and insert the Arabic numeral '3'.

- ch 2 reg 56(2) amending a prescription
- This provision states that a pharmacist may amend a prescription only if the information is not inconsistent with the instructions on a prescription.
- If there is an error in the original instructions, then an amendment will always be inconsistent with those original instructions. Therefore, under ch 2 reg 56(1) the amendment would not be allowed.
- This puts the patient at risk of harm from a prescribing error which is not permitted to be corrected by a pharmacist amending a prescription. The provision is therefore inconsistent with the purposes of the Medicines and Poisons Bill 2019 (Qld) listed in cl 3.
- In ch2 reg 56(2) omit the words 'but only if the information in not inconsistent with the instructions on the prescription.'

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- ch 2 reg 56(3)(a) – the patient is required to consent to amendment of a prescription
- A pharmacist is not authorised to amend a prescription if a patient does not provide consent. Therefore, an amendment would not be allowed under ch 2 reg 56(1) if there is an error in the original instructions on a prescription and the patient does not provide consent.
- This puts the patient at risk of harm from a prescribing error which is not permitted to be corrected by a pharmacist amending a prescription. The provision is therefore inconsistent with the purposes of the Medicines and Poisons Bill 2019 (Qld) listed in cl 3.
- In ch 2 reg 56, omit reg 56(3)(a).

III Conclusion

This submission has identified and considered numerous issues with the proposed regulatory framework. The authors encourage the committee to consider this submission and implement any changes which the committee consider are necessary. This will ensure that the regulatory framework achieves its stated objectives. The authors would like to thank the committee for their time in considering this submission.

IV References

Explanatory Notes, Medicines and Poisons Bill 2019 (Qld)

Medicines and Poisons Bill 2019 (Qld)

Medicines and Poisons (Medicines) Regulation 2019 (Qld)

Queensland, *Parliamentary Debates*, Legislative Assembly, 14 May 2019, 1522-1524 (Steven Miles, Minister for Health and Minister for Ambulance Services)

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